

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 C.F.R. § 101.93

RECEIVED
12/4/98

This notification is being filed on behalf of Natural Balance, Inc., 3136 N. Commerce Court, P. O. Box 8002, Castle Rock, CO 80104 - 8002, which is the manufacturer of the product which bears the statements identified in the Notification. This Notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling statements appears is 5-HTP.

The text of each structure-function statement for which notification is now being given is:

- Statement 1: *Calming Neuro-nutrient Enhances Mood, Promotes Sleep*
- Statement 2: *Clinical studies show that the nutrient 5-HTP (5-hydroxytryptophan) helps increase your levels of serotonin, the brain chemical involved with keeping you on a steady course, relaxed and calm.*
- Statement 3: *Adequate serotonin levels also play an important role in helping you sleep more soundly and may even help reduce your cravings for carbohydrates.*
- Statement 4: *All natural 5-HTP from Natural Balance combines 5-HTP and Vitamin B-6 an important co-factor in the production of serotonin.*
- Statement 5: *Lab tested for purity and potency, 5-HTP really can help you sleep better and improve your sense of well-being.*
- Statement 6: *Together, these natural ingredients interact to help increase your body's production of the calming neuro-transmitter serotonin.*
- Statement 7: *5-HTP will help you feel more relaxed, sleep better and enjoy a more positive outlook.*
- Statement 8: *5-HTP (5-hydroxytryptophan). A natural compound known to help increase the production of serotonin, a chemical in the brain which plays a key role in keeping you calm, improving your mood, helping you sleep more soundly, may even reduce cravings for carbohydrates.*
- Statement 9: *Vitamin B-6. An essential nutrient which helps synthesize serotonin in the brain.*
- Statement 10: *5-HTP - Exciting Natural Formula Helps Improve Your Mood, Sleep Better*
- Statement 11: *5-HTP - Helps Increase Serotonin Levels*

The following summary identifies the dietary ingredient(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	5-HTP (5-hydroxytryptophan)
2.	5-HTP (5-hydroxytryptophan)
3.	5-HTP (5-hydroxytryptophan)

4. *Vitamin B-6*
5. *5-HTP (5-hydroxytryptophan)*
6. *5-HTP (5-hydroxytryptophan) and Vitamin B-6*
7. *5-HTP (5-hydroxytryptophan)*
8. *5-HTP (5-hydroxytryptophan)*
9. *Vitamin B-6*
10. *5-HTP (5-hydroxytryptophan)*
11. *5-HTP (5-hydroxytryptophan)*

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Label – 30 Capsules Printed Box – 60 Capsules Label – 60 Capsules</i>
2.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Printed Box – 60 Capsules</i>
3.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Printed Box – 60 Capsules</i>
4.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Printed Box – 60 Capsules</i>
5.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Printed Box – 60 Capsules</i>
6.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Printed Box – 60 Capsules</i>
7.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Label – 30 Capsules Printed Box – 60 Capsules Label – 60 Capsules</i>
8.	<i>5-HTP</i>	<i>Printed Box – 30 Capsules Printed Box – 60 Capsules</i>

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5-HTP

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| 9. | 5-HTP | <i>Printed Box – 30 Capsules</i>
<i>Printed Box – 60 Capsules</i> |
| 10. | 5-HTP | <i>Printed Box – 30 Capsules</i>
<i>Printed Box – 60 Capsules</i> |
| 11. | 5-HTP | <i>Printed Box – 30 Capsules</i>
<i>Label – 30 Capsules</i>
<i>Printed Box – 60 Capsules</i>
<i>Label – 60 Capsules</i> |

I, Patricia L. Vazquez, am authorized to certify this Notification on behalf of Natural Balance, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Natural Balance, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 12.1.98

By: Patricia L. Vazquez

Title: Director, Regulatory Affairs